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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/081,736	02/20/2002	Justin R. Fallon	BURF-P02-006	2816

28120 7590 01/19/2007
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EXAMINER

CHERNYSHEV, OLGA N

ART UNIT	PAPER NUMBER
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1649

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/19/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/081,736	Applicant(s) FALLON ET AL.	
	Examiner Olga N. Chernyshev	Art Unit 1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 November 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13, 16, 32 and 34-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13, 16, 32 and 34-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-----------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>12/21/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 22, 2006 has been entered.

Response to Amendment

2. Claim 13 has been amended as requested in the amendment filed on September 25, 2006. Following the amendment, claims 13, 16, 32 and 34-39 are pending in the instant application.

Claims 13, 16, 32 and 34-39 are under examination in the instant office action.

3. The Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

5. Applicant's arguments filed on September 25, 2006 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

Claim Rejections - 35 USC § 102

6. Claims 13, 16 and 32-38, as amended, stand rejected under 35 U.S.C. 102(b) as being anticipated by Ruoslahti et al., US Patent No. 5,654,270 for reasons of record in previous communications of record.

In Response filed on September 25, 2006, Applicant reiterates the arguments already made of record and further submits that current amendment to claim 13 to recite a cell “in need of activation of a membrane” distinguishes the claimed subject matter from disclosure of the Ruoslahti et al. document. Specifically, Applicant argues that “Ruoslahti et al. fail to teach or suggest a method which involves use of a cell in need of activation of membrane or an amount of biglycan therapeutic effective to potentiate agrin-induced phosphorylation of MuSK” (p. 4 of the Response). Applicant’s arguments have been fully considered but are not persuasive for the reasons of record fully explained earlier and briefly repeated below.

As fully explained in the previous communications of record, because the instant claims are broadly drawn to a method for activating a membrane of a cell, wherein the method step is limited to contacting the cell with biglycan, and because the patent of Ruoslahti et al. expressly describes administration of biglycan to a wound comprising cells expressing MuSK, one would reasonably expect that such contact of biglycan and cell membrane would lead to activation of MuSK, absence evidence to the contrary. Adding the limitation describing the cell as “in need of activation of membrane” does not affect the scope of the claimed subject matter because it is not clear what constitutes a cell’s need of activation of a membrane, see reasons of record in section 9 below. Moreover, claim 13 currently does not recite the effective amount for MuSK activation. Should claim 13 recite such concentration, claims 13, 16, 32 and 34-39 would be allowable

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because this would distinguish the instant claims and the prior art of record, and also would support the enablement of the instant invention for that particular concentration in view of biphasic effect of biglycan, see section 6 of the office action mailed on June 22, 2006.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 13, 16, 32 and 34-39 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

9. Claim 13, as amended is vague and indefinite for recitation “a cell in need of activation of a membrane”, which renders the claim indefinite because it is unclear whether the limitation is part of the claimed invention. It is not obvious how to ascertain the need of a cell’s membrane activation as the need itself is not clearly defined. Clarification is required.

10. Claims 16, 32 and 34-39 are indefinite for being dependent from indefinite claim.

Conclusion

11. No claim is allowed.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (571) 272-0870.

The examiner can normally be reached on 8:00 AM to 5:00 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Olga N. Chernyshev, Ph.D.
Primary Examiner
Art Unit 1649

January 12, 2007